

## **AMENDMENT 1**

**SOLICITATION NO: NHLBI-CSB-WH-13-01-ST**

**SOLICITATION TITLE: Towards Maximizing the Scientific Return on the Women's Health Initiative Biological Resource**

**EFFECTIVE DATE: May 7, 2012**

**ISSUED BY:**

**National Heart, Lung, and Blood Institute, NIH  
Office of Acquisitions  
6701 Rockledge Drive, Suite 6016, MSC 7902  
Bethesda, Maryland 20892-7902**

**Point of Contact: Stacy C. Turner, Contracting Officer, at [turners@nhlbi.nih.gov](mailto:turners@nhlbi.nih.gov)**

**The above numbered solicitation is amended as set forth below. All other terms and conditions of the solicitation remain unchanged.**

### **DESCRIPTION OF AMENDMENT**

**PURPOSE: To revise the solicitation as follows:**

- A. Revise Article C.2. Reporting Requirements.**
- B. Provide Attachment 1, Packaging and Delivery of Proposals.**
- C. Provide Attachment 2, Proposal Intent Response Sheet and extend due date.**
- D. Provide active link to Attachment 4, Section K - Representations, Certifications, and Other Statements of Offerors.**
- E. Add Attachment 12.A., Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet and active link.**
- F. Provide a completed chart at Article F.2. Deliveries, paragraph a.**
- G. Additional information is added at H.14. Information and Physical Access Security.**
- H. Add Article H.21. Multiple Principal Investigators**

**This amendment revises the solicitation as stated on the following page.**

**A. REFERENCE: Article C.2. Reporting Requirements, pages 6 & 7 only.**

**CHANGED TO:**

In addition to those reports required by other terms of the contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of the resulting contract:

*Note: No deliverable will be accepted unless it conforms to Section 508 of the Rehabilitation Act of 1973.*

**1. Program Plan**

A Final Program Plan, including a brief protocol (outline of study hypothesis and approach), operating procedures, and schedule for each stage of the Program Plan shall be submitted thirty days after contract award for review and approval. The plan shall identify technical risks and critical decision points that are expected to result, and include a one page graphic that reflects, task-by-task, when the key milestones of the contract work will be met. The laboratory component and epidemiologic/statistical component should be clearly indicated in the plan and graphic. Any subsequent changes made by the Contractor, to the approved Plan, shall be submitted to the NHLBI for review and approval. The Program Plan should not exceed 15 double-spaced pages; additional materials can be added as an appendix.

**2. Abstracts and Manuscripts**

Abstracts and Manuscripts in progress and proposed for publication shall be provided in accordance with the WHI Publications and Presentations Policy ([www.whiscience.org](http://www.whiscience.org)).

**3. Reports**

Reports shall be submitted in approximately months 6, 11, 18, 23 and 30 after award, plus a final report on or before the expiration date of the contract (exact dates to be agreed with NHLBI and documented in the Final Program Plan). Reports in months 6, 18, and 30 are Interim Progress Reports; reports in months 11 and 23 are Annual Technical Reports, and the report due by the end of the contract is the Final Technical Report.

**3A. Interim Progress Reports**

Interim Progress Reports document and summarize all work results for the previous period. This report shall be in sufficient detail to explain comprehensively the results achieved. The report should be in letter form (2-3 pages) to both the Contracting and Project Officers. The report should include progress for the elapsed months, problems encountered during the period, a discussion of milestones met or missed, a summary of activities planned for the next period, and summarize and reference manuscripts in progress, submitted, or published.

**3B. Annual Technical Reports**

This report shall document and summarize all work results for the period covered. Specifically, the report shall include:

- Face page to include contract number, title, period of performance being reported, Contractor's name and address, telephone and facsimile numbers, and date of submission.

- An executive summary, to include:
  - A statement of intended work for the reporting period per program plan;
  - A brief overview of the work actually completed for the reporting period;
  - A brief overview of any problems (technical or financial) that occurred during the reporting period and whether or not they have been resolved;
- Updates to the Program Plan, if any
- A summary of activities planned for the next reporting period
- A description of:
  - The work performed during the reporting period, including major relevant findings;
  - The materials and methods pertaining to the work;
  - The relationship between the accomplishments made relative to the goals, objectives, and milestones of the statement of work; and
  - Problems encountered and their resolution.
- Copies of manuscripts (published or unpublished) derived from research under the contract and copies of all abstracts, manuscripts, preprints and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period
- Manuscripts and publications resulting from this work must cite the support received from this award
- An update of the Dissemination Plan, including time line and discussion of dissemination made to date
- Full disclosure of intent to file patent applications in the U.S. or outside of the U.S. on materials, animal models, or procedures derived or established by the work supported under this contract
- Full disclosure of patent applications filed in the U.S. or outside of the U.S. as well as copies of patent applications
- Full disclosure of any efforts to transfer the technology or receipt of support from outside entities interested in future access, partnering, or license to the developing technologies.

### 3C. Final Technical Report

This report shall consist of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved, and the final Dissemination Plan including dissemination to date. The final report shall be submitted on or before the last day of the contract performance period.

#### 4. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

#### 5. Initial Data Submission

The contractor will be required to prepare and submit a dataset of the laboratory data generated under this contract with documentation to the WHI Clinical Coordinating Center in electronic format e.g.CD or other format as requested by the WHI Clinical Coordinating Center. After acceptance of the laboratory data by the WHI Clinical Coordinating Center, the complete dataset pertinent to the study will be provided to the Contractor.

#### 6. Final Data Submission

The Contractor will be required to prepare and submit a final dataset of data generated under this contract with documentation to the WHI Clinical Coordinating Center and/or dbGAP, BioLINCC, or other repository as directed by NHLBI. The dataset and documentation shall be submitted in electronic format e.g.CD or other format as requested by the WHI Clinical Coordinating Center on or before the expiration date of this contract. The final dataset will indicate the curated data.

#### 7. Other Reports

##### 1. Subset Differences, if applicable

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

##### 2. Invention Reporting Requirement

All reports and documentation required by [FAR Clause 52.227-11/FAR Clause 52.227-11 (Deviation)/FAR Clause 52.227-13] including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final

invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.2. DELIVERIES of this contract to:

NHLBI, Office of Acquisitions  
Attn: WHI Contracting Officer  
6701 Rockledge Drive, Suite 6016, MSC 7902  
Bethesda, Maryland 20892 -7902

**B.** Attachment 1, Packaging and Delivery of Proposals is attached herein.

**C.** Attachment 2, Proposal Intent Response Sheet is attached herein. The due date for submission of this completed form is extended to Tuesday, May 15, 2012.

**D.** Attachment 4, Section K - Representations, Certifications, and Other Statements of Offerors is available at <http://oamp.od.nih.gov/DGS/FORMS/sectionk.pdf>.

**E.** Attachment 12.A., Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet is added and is available at <http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls>.

**F.** The following completed chart is added at F.2.a.

Item	Description	Quantity	Delivery Schedule
1.	Program Plan	1-CO & 1-COR	30 days after contract award
2.	Abstracts & Manuscripts	Per WHI policy (whiscience.org)	Per WHI policy (whiscience.org)
3.	Interim Progress Reports	1-CO & 1-COR	6, 18 & 30 months after contract award
4.	Annual Technical Reports	1-CO & 1-COR	11 & 23 months after contract award
5.	Final Technical Report	1-CO & 1-COR	On or before contract expiration date
6.	Summary of Salient Results	1-CO & 1-COR	On or before contract expiration date
7.	Initial Data Submission	1-WHI CCC	45 days prior to contract expiration date
8.	Final Data Submission	1-WHI CCC & 1-Repository specified by the NHLBI	On or before contract expiration date
9.	Subset Differences	See Annual & Final Tech Rpt quantities	See Annual & Final Technical Report delivery schedules
10.	Invention Reporting Requirement	1-CO & 1-OPERA	Reference Invention Reporting Requirement description for due

			dates
11.	Leadership Plan, if multiple Principal Investigators are proposed	Draft w/Original Proposal. Updates: 1-CO & 1-COR	Draft with original proposal & updates, as needed

**G.** The following text is added under H.14. Information and Physical Access Security.

**1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)**

a. Information Type:

☐ Administrative, Management and Support Information:

☒ Mission Based Information:

b. Security Categories and Levels:

Confidentiality Level: ☒ Low ☐ Moderate ☐ High  
Integrity Level: ☒ Low ☐ Moderate ☐ High  
Availability Level: ☒ Low ☐ Moderate ☐ High

Overall Level: ☒ Low ☐ Moderate ☐ High

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

d. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

☐ Level 6: Public Trust - High Risk. Contractor/subcontractor employees

assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

☐ Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

☒ Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

**H. H.21.** Multiple Principal Investigators, is added as follows. Note that a draft Leadership Plan is to be submitted with proposals which include multiple Principal Investigators.

#### **H.21. MULTIPLE PRINCIPAL INVESTIGATORS**

The NIH awarded this contract as a multiple Principal Investigators project. The Key Personnel Article in SECTION G of this contract designates the Contact Principal Investigator and all other Principal Investigators.

Contracts designating multiple Principal Investigators require a current Leadership Plan with updates as needed. The Contractor's Leadership Plan, dated [*To be finalized at award, if applicable.*], (and as modified thereafter, in accordance with the Reporting Requirements Article in SECTION C of this contract), is hereby [incorporated by reference OR included as an Attachment in Section J of this contract.]